NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ORTHO-MCNEIL PHARMACEUTICAL, INC., plaintiff,	Civil Action Nos. 04-1689 and 06-757 Consolidated Cases
v.	**OPINION**
MYLAN LABS, INC., et al., defendants.	

CHESLER, District Judge

I. INTRODUCTION

This matter comes before the Court on the motion of plaintiff, Ortho-McNeil Pharmaceutical, Inc. ("Ortho"), for partial summary judgment on defendants Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc.'s (collectively "Mylan") inequitable conduct affirmative defense. [Docket Entry No. 54.] For the reasons that follow, Ortho's motion is **GRANTED**.

II. BACKGROUND

This is a patent infringement case brought under the Hatch Waxman Act. Plaintiff Ortho claims that, on April 23, 1985, the United States Patent and Trademark Office ("PTO") issued United States patent number 4,513,006 (the "'006 patent"), entitled ANTICONVULSANT SULFAMATE DERIVATIVES, to McNeilab, Inc. as assignee of inventors Dr. Bruce E.

Maryanoff and Dr. Joseph F. Gardocki.[1] (Compl. at ¶ 10.) McNeilab is Ortho's corporate predecessor. (Id.) The claims of the '006 patent cover the drug topiramate, pharmaceutical compositions containing topiramate, and a method of using topiramate to treat convulsions. (Id. at ¶ 11.) Ortho holds an approved New Drug Application ("NDA"), under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 335(a), for topiramate tablets and topiramate capsules, which are marketed in the United States as the anticonvulsant known as TOPAMAX®. (Id.) The PTO has granted an interim extension of the '006 patent for one year, and Ortho has applied to have it extended further, possibly until as late as September 26, 2008. (Id. at ¶ 13.)

Mylan has filed an Abbreviated New Drug Application ("ANDA"), pursuant to Section 505(j) of the FFDCA, to market topiramate 25, 50[2], 100, and 200 mg. tablets before the expiration of the '006 patent. (Id. at ¶ 14.) In its ANDA, Mylan claims that the '006 patent is invalid and, therefore, that none of its claims would be violated by Mylan's manufacture, use, offer for sale, and sale of topiramate. (Id. at ¶ 15.) On March 2, 2004, Mylan served Ortho with notice of its position and intent to seek approval to market topiramate before the expiration of the '006 patent. (Id. at ¶ 16.)

Ortho filed its complaint on April 12, 2004, claiming that Mylan's ANDA filing

---

[1]Hereinafter the term "applicants" shall refer to Dr. Maryanoff and David Levy, Esq., the patent attorney involved in prosecuting the '006 patent.

[2]The Complaint filed in Civil Action No. 04-1689 alleged infringement of the '006 patent based on Mylan's efforts to obtain an ANDA with respect to topiramate 25, 100, and 200 mg. tablets. Mylan subsequently amended its ANDA to include 50 mg. tablets and Ortho filed another lawsuit to address that dosage, under Civil Action No. 06-757. On May 17, 2006, Magistrate Judge Bongiovanni entered an Order consolidating these matters. [Civil Action No. 04-1689, Docket Entry No. 129.]

constitutes infringement of the '006 patent (id. at ¶ 18), and that such infringement was done knowingly (id. at ¶¶ 20-22). Ortho seeks a declaratory judgment that the effective date of the approval of Mylan's ANDA can be no earlier than the expiration of the '006 patent as extended (id. at ¶ 19), and reasonable attorneys' fees (id. at ¶ 24).

Mylan filed its Answer on May 20, 2004. [Docket Entry No. 4.] Its second affirmative defense stated that "[t]he Complaint fails to state a claim upon which relief can be granted." (Answer at 4, Third Defense – Failure to State a Claim.) Mylan amended its Answer and Affirmative Defenses on May 16, 2005. [Docket Entry No. 42.] The amendment expanded Mylan's Third Affirmative Defense to allege that the '006 patent was invalid because Dr. Maryanoff, a named inventor of topiramate, engaged in "pervasive and ongoing inequitable conduct, all for the purpose of inducing the PTO to issue a patent on claims that did not meet the statutory requirements for patentability." (Am. Answer at 4-5.) Namely, Mylan alleged as follows:

> a. Dr. Maryanoff withheld from the PTO the results of testing conducted at Ortho on a prior art compound that directly contradicted arguments advanced on behalf of Maryanoff to the PTO in order to distinguish topiramate over the same prior art compound;
>
> b. Dr. Maryanoff withheld from the PTO material, non-cumulative prior art relied on by him in conceiving of the claimed inventions; and
>
> c. Dr. Maryanoff falsely named Dr. Joseph Gardocki as a co-inventor when he knew that Gardocki had done nothing to qualify him as an inventor under 35 U.S.C. § 115. This error in naming Gardocki as an inventor cannot be corrected under 35 U.S.C. § 256 because the error arose out of the deliberate conduct by Maryanoff that was intended to deceive the PTO.

(Id. at ¶¶ 2(a)-(c).) Mylan claims this information would have been material to a patent examiner's analysis and, had Ortho submitted it, the examiner would have rejected the patent application. (Id. at ¶ 3.) Mylan claims that, as a result of this intentional conduct, the '006 patent is void and unenforceable. (Id. at ¶ 4.)

III. DISCUSSION

A. Summary Judgment Standard

Summary judgment is appropriate where there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. See Fed.R.Civ.P. 56. When considering a summary judgment motion, the Court must view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion. In re Flat Glass Antitrust Litig., 385 F.3d 350, 357 (3d Cir. 2004).[3] The existence of a "mere scintilla of evidence in support of [a] nonmovant's position will be insufficient" to withstand a summary judgment motion. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986). In determining whether more than a scintilla is extant, a court must "not weigh the evidence or make credibility determinations; these tasks are left to the fact-finder." Boyle v. County of Allegheny, Pa., 139 F.3d 386, 393 (3d Cir. 1998).

B. The Law of Inequitable Conduct

The doctrine of inequitable conduct provides that "[a] patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the

[3]In patent cases, district courts apply the summary judgment standard under the law of their own circuits. See CollegeNet Inc. v. ApplyYourself Inc., 418 F.3d 1225, 1230 (Fed. Cir. 2005).

PTO during prosecution." Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1313 (Fed. Cir. 2006). An inequitable conduct claim requires clear and convincing evidence of (1) affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information; and (2) the intent to deceive. Alza Corp. v. Mylan Labs., Inc., 391 F.3d 1365, 1373 (Fed. Cir. 2004). The party asserting the inequitable conduct claim has the burden of proving "a threshold level of materiality and intent by clear and convincing evidence." Digital Control, Inc., 437 F.3d at 1313.

As a general matter, a party may show materiality by demonstrating that "a reasonable examiner would have considered such prior art important in deciding whether to allow the parent [sic] application." Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1363 (Fed. Cir. 2003) (quoting Driscoll v. Cebalo, 731 F.2d 878, 884 (Fed. Cir. 1984) (internal citations omitted)). Rule 56 of the PTO Rules provides:

> [I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
>
> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
>
> (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.
>
> A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

37 C.F.R. § 1.56(b) (2006).[4]

A showing of materiality "does not presume intent, which is a separate and essential component of inequitable conduct." GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1274 (Fed. Cir. 2001) (quoting Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 552 (Fed. Cir. 1990)). "Intent to deceive can not be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent." Hebert v. Lisle Corp., 99 F.3d 1109, 1116 (Fed. Cir. 1996). In short, there must be some evidence, other than the materiality of the allegedly omitted information, of an intent to deceive the PTO.

Once this threshold showing of "materiality and intent" is made "by clear and convincing evidence," the Court must consider whether or not the alleged conduct "amounts to inequitable conduct by balancing the levels of materiality and intent, 'with a greater showing of one factor allowing a lesser showing of the other.'" Digital Control, Inc., 437 F.3d at 1313 (quoting Union Pac. Co. v. Chesapeake Energy Corp., 236 F.3d 684, 693 (Fed. Cir. 2001)). This analysis contemplates a sliding scale whereby the requisite level of intent becomes lower as the materiality of the information becomes greater. Thus, where "a reasonable examiner would

---

[4]Three additional standards may be applied in determining materiality:

> These standards include[]: the objective "but for" standard, where the misrepresentation was so material that the patent should not have issued; the subjective "but for" test, where the misrepresentation actually caused the examiner to approve the patent application when he would not otherwise have done so; and the "but it may have" standard, where the misrepresentation may have influenced the parent [sic] examiner in the course of prosecution.

Digital Control, Inc., 437 F.3d at 1315 (citing Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1362 (Fed. Cir. 1984)).

merely have considered particular information to be important but not crucial to his decision" the requisite finding of intent must be high; conversely, where an objective "but for" standard of materiality is shown, "a lesser showing of facts from which intent can be inferred may be sufficient." Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1362 (Fed. Cir. 1984).

C. Mylan's Inequitable Conduct Affirmative Defense

In support of its inequitable conduct affirmative defense, Mylan claims that Ortho (1) made misrepresentations and omissions with respect to a prior art reference called the Kochetkov isomer[5]; (2) failed to disclose comparative testing of acetozolamide, known anticonvulsant; (3) failed to disclose the true role of a particular inventor; and (4) failed to disclose Dr. Maryanoff's reliance on the works of Jenkins and Shuman.

i. The Kochetkov Prior Art References

The "Kochetkov isomer" is a compound discussed in a series of articles by a group of Soviet scientists, which has a chemical structure similar to that of topiramate. Topiramate and the Kochetkov isomer both are 6 carbon sugars, having four of their five hydroxyl groups protected by isopropylidene substituents, leaving available for further attachment only a single CH_2OH group. (Declaration of David J. Harth ("Harth Decl."), Ex. I, Anderson Expert Report at ¶ 19.) Both molecules are pure sugar derivatives, uncomplicated by the presence of a non-sugar moiety. (Id.) The two molecules differ in that the CH_2OH group in the Kochetkov isomer shares its point of attachment at the main ring of the sugar molecule with a hydrogen atom, while in

[5]At oral argument, counsel for Mylan described this argument as the main basis for its inequitable conduct claims, and the other bases as just "icing on the cake."

topiramate the CH_2OH group carries an oxygen substituent in place of hydrogen. (Id.) Dr. Maryanoff stated the Kochetkov sulfamate is a "constitutional isomer" of topiramate. (Harth Decl., Ex. D, Maryanoff Dep. Tr. at 159:4-20.)

The applicants for the '006 patent submitted the Kochetkov articles to the PTO and the application was initially rejected based on the articles based on 35 U.S.C. Section 102 (anticipation) and, alternatively, Section 103 (obviousness). (Declaration of Eric L. Lohrenz ("Lohrenz Decl."), Ex. J at 36.) In response, the applicants argued:

> Firstly, it should be appreciated that any rejection made on [the Kochetkov articles] can only be under 35 U.S.C. 103. While the structures in [the Kochetkov articles] are somewhat unclear and difficult to compare to Applicants' compounds, a detailed consideration of the structures reveals the fact that Applicants are claiming entirely different structures.
>
> . . .
>
> Of particular note in comparing the above two general structures are the pendant sulfamate moieties. In Kochetkov AR - AU, the sulfamate is connected in every instance to the single carbon of the pyranose ring which is not itself attached to the methylenedioxy moieties. For example, see formulas (II) and (III) and (VI) of AR; formulas (I), (III) and (V-VII) of AS; formula (XIV) of AT; and formula (VI) of AU. In all compounds of the present invention, the sulfamate moiety is attached to the carbon of the pyranose ring which also has attached to it the R_2 moiety.

(Id., Ex. J at 39-40.) Thus, the applicants argued that the anticipation rejection under Section 102 was inappropriate because topiramate and the Kochetkov compounds were not the same, but were "entirely different."

In response to the alternative basis of rejection, Section 103, the applicants argued the requirements for a prima facie case of obviousness were missing. They argued:

> It should be noted that the utility disclosed in the Kochetkov references AR-AU is extremely limited and narrow. These

> compounds are merely taught as being convenient derivatives of monosaccharide sulfates to allow separation of such sulfates from each other with regeneration of the original sulfate thereafter. No teaching is provided for any actual utility of the sulfamates or sulfates described in AR - AU and it is respectfully submitted that there is no motivation for one skilled in the art reading AR - AU to go beyond the pyranoses disclosed therein to arrive at Applicants invention.

(Id., Ex. J at 40-41.) The applicants' argument, therefore, was limited to what the Kochetkov references disclosed and did not address the differences between the properties of the Kochetkov compounds and topiramate. Based on these arguments, the '006 patent was issued.

In support of its invalidity affirmative defense, Mylan claims that applicants for the '006 patent committed inequitable conduct by (1) stating in their application that the Kochetkov isomer had an "entirely different structure" from topiramate (DS at ¶ 12), (2) withholding test data showing that the Kochetkov isomer, like topiramate, exhibited anticonvlsive properties (id. at ¶¶ 13-14), and (3) arguing to the PTO that the Kochetkov isomer was only of "limited utility" and that the patent on topiramate should be allowed because the Kochetkov isomer was ineffective as an anticonvulsant (Id. at ¶ 16). But for these misrepresentations and omissions, Mylan argues, the examiner would have found the claimed invention to be obvious.

Ortho argues summary judgment in its favor is proper as to this theory because it submitted the Kochetkov isomer to the PTO in connection with the application for the '006 patent; all of the representations regarding the Kochetkov isomer were accurate; and the comparative testing related to the Kochetkov isomer was not material to the patent examiner's inquiry. With regard to materiality, Ortho argues the applicants addressed the denial based on the Kochetkov prior art references by successfully arguing that a prima facie case of obviousness was

never established. Given that the examiner ultimately granted the application based upon his apparent acceptance of the applicants' argument that no prima facie case had been established, Ortho argues such testing was never relevant to the examiner's inquiry and, therefore, was not material.

a. Alleged Misrepresentations Regarding the Kochetkov Isomer

The structure of the Kochetkov references were before the patent examiner at the time the '006 patent was granted. Indeed, they were the foundation for the initial denial of the application. The applicants' response to the denial, namely the argument that the Kochetkov isomer had an "entirely different structure," was advocacy and was accompanied by an explanation of those differences. (See Lohrenz Decl., Ex. J at 39-40.) Incidentally, Mylan does not dispute the accuracy of the substantive distinction submitted to the PTO in response to the denial. The examiner, who is presumed to be skilled in the art and able to draw his or her own conclusions about the similarities and differences between the claimed invention and the prior art, see In re Lee, 277 F.3d 1338, 1345 (Fed. Cir. 2002), was free to accept or reject the applicants' position regarding the Kochetkov isomer. In short, the applicants' efforts to argue that the claimed invention was not anticipated by the prior art does not rise to the level of a material misrepresentation. See Akzo N.V. v. U.S. Int'l. Trade Comm'n., 808 F.2d 1471, 1482 (Fed. Cir. 1986) ("The mere fact that [the applicant] attempted to distinguish the [claimed] process from the prior art does not constitute a material omission or misrepresentation. The examiner was free to reach his own conclusion regarding the [claimed] process based on the art in front of him."). The Court is satisfied, therefore, that summary judgment is appropriate as to this argument.

b. Alleged Failure to Disclose Comparative Testing

Consideration of whether or not the applicants improperly withheld comparative testing of the Kochetkov isomer involves a review of the PTO's practice in determining obviousness. As an initial matter, an applicant is only required to disclose in a patent application information that is material to the examiner's determination. 37 C.F.R.§ 1.56(a). The question here is whether or not the comparative testing was material to the examiner's analysis.

In determining obviousness, the PTO employs a two-step analysis. First, it considers whether or not the prior art demonstrates a "prima facie" case of obviousness. The prima facie case is a procedural tool that requires that the examiner initially produce evidence sufficient to support a ruling of obviousness. In re Kumar, 418 F.3d 1361, 1366 (Fed. Cir. 2005) (citations omitted). To establish a prima facie case of obviousness, there must be (1) some suggestion or motivation in the prior art references or "in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine" its teachings; (2) a reasonable expectation of success in doing so; and (3) the prior art references "must teach or suggest all the claim limitations" of the claimed invention. Manual of Patent Examining Procedures ("MPEP") § 706.02(j) (2005). "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure." Id.

In In re Dillon, 919 F.2d 688 (Fed. Cir. 1990), the Court of Appeals for the Federal Circuit addressed the extent to which a prior art reference must motivate one reasonably skilled in the art to make the claimed invention sufficient to establish a prima facie case of obviousness. The Dillon court held "the lack of any disclosure of useful properties for a prior art compound

may indicate a lack of motivation to make related compounds, thereby precluding a prima facie case." Id. at 698.[6] The rationale for this is set forth in In re Stemniski, 444 F.2d 581 (C.C.P.A. 1971), which held that a prior art reference is a reference only for what it discloses and consequently, if the reference discloses no utility, then it cannot support a threshold showing of obviousness. The Stemniski Court stated:

> Where the prior art reference neither discloses nor suggests a utility for certain described compounds, why should it be said that a reference makes obvious to one of ordinary skill in the art an isomer, homolog or analog or related structure, when that mythical, but intensely practical, person knows of no 'practical' reason to make the reference compounds, much less any structurally related compounds?

444 F.2d at 586. Under Stemniski and Dillon, therefore, an examiner could find that a prior art reference that teaches a structurally similar compound, yet discloses no "useful properties," would not motivate one reasonably skilled in the art to make the claimed compound. This would preclude a prima facie case of obviousness and, thus, the necessity of further evidence related to the prior art.

If a prima facie case of obviousness is made, then the examiner proceeds to the second step of the prima facie analysis and the burden shifts to the applicant "to come forward with evidence or argument in rebuttal." In re Kumar, 418 F.3d at 1366. Rebuttal evidence may include proof:

> that the claimed invention achieved unexpected results relative to the prior art, In re Geisler, 116 F.3d 1465, 1469-70 (Fed. Cir. 1997); that the prior art teaches away from the claimed invention,

---

[6]The Dillon Court qualified its holding by stating "it is not correct that similarity of structure and a suggestion of *the activity of an applicant's compounds* in the prior art are necessary before a prima facie case is established." 919 F.2d at 698 (italics in original).

> id. at 1471; that objective evidence (e.g., commercial success) supports the conclusion that the invention would not have been obvious to a skilled artisan, Piasecki, 745 F.2d at 1475; or that the prior art did not enable one skilled in the art to produce the now-claimed invention, In re Payne, 606 F.2d 303, 314-15 (C.C.P.A. 1979).

Id. at 1368.

Rather than submit rebuttal evidence, the applicants made a Dillon-type argument. They argued the utility "disclosed in" the Kochetkov references was narrow, that the prior art references merely "taught as being convenient derivatives of monosaccharide sulfates to allow separation of such sulfates from each other with regeneration of the original sulfate thereafter," and that "[n]o teaching is provided for any actual utility of the sulfamates or sulfates described in AR - AU . . . ." (Lohrenz Decl., Ex. J at 40-41) (emphasis added). Thus, they argued, the prima facie case had not been established and "there is no motivation for one skilled in the art reading AR - AU to go beyond the pyranoses disclosed therein to arrive at Applicants[']s invention." (Id., Ex. J at 40-41.) The argument attacks the first factor of a finding of the prima facie case, namely that the prior art reference would motivate one of reasonable skill in the art to make the claimed invention. See MPEP at § 706.02(j). Based on this argument, the '006 patent was granted.

It is apparent, therefore, that the PTO was persuaded that a prima facie case of obviousness was not established and the Court is satisfied that the applicants were not obligated to come forward with evidence beyond the teachings of the prior art references. The testing of the Kachetkov isomer would not have been material until the applicants sought to rebut a finding by the PTO that there is was a prima facie case of obviousness. That did not occur here and, in the absence of the patentee seeking to rebut a prima facie case of obviousness, the Court is

persuaded the applicants were not obligated to supply additional information because it was not material to the examiner's inquiry. For this reason, summary judgment is appropriate as to Mylan's inequitable conduct argument based on the applicants' failure to supply comparative test results related to the Kochetkov isomer to the PTO.

ii. Testing of Acetozolamide

Mylan claims that Dr. Maryanoff performed comparative testing on two known anticonvulsants: phenytoin and acetozolamide. (Harth Decl., Ex. L, Levy Dep. Tr. at 48:11-49:12; 54:21-56:12.) It claims that while phenytoin's chemical structure is different from topiramate, acetazolamide contains a SO_2NH_2 moiety, different from topiramate's moiety only by the presence of an additional oxygen atom. (Id. at Ex. T, Danishefsky Dep., Ex. 10.) Mylan claims that acetazolamide, a sulfonamide, is an effective anticonvulsant (Harth Decl., Ex. N., Supuran Expert Report at ¶¶ 9-11; Mylan's Br. at 20), yet Maryanoff disclosed only his work with phenytoin, and not acetazolamide, to the PTO (Harth Decl., Ex. H, '475 Application at 7, *ll.* 5-7 (OMP 072456); Ex. P, '006 patent, col. 4, *ll.* 21-23). Mylan states "[a]t trial, Dr. Supuran, Mylan's expert in medicinal chemistry, will testify that it would have been obvious to one of ordinary skill in the art that the sulfamate topiramate also would act as a carbonic anhydrase inhibitor, and thus potentially as an anticonvulsive." (Mylan's Br. at 20.)[7] Mylan argues,

---

[7]While the Court shall not engage in a credibility determination with respect to Dr. Supuran's testimony, the Court is dubious about its value. Dr. Supuran's opinion that acetazolamide is material prior art assumes that one reasonably skilled in the art arrived at topiramate *by chance*, and does not appear to deal with whether or not one reasonably skilled in the art would be *motivated* to make topiramate based on acetazolamide or the acetazolamide testing. The colloquy at deposition was as follows:

> Q. But you don't have in mind any particular prior art that would have led a person of ordinary skill to the specific

therefore, that the disclosure of this information would have been an adequate basis for rejecting claims 6, 7, and 8 which claimed the use of topiramate as an anticonvulsant. (Id. at 19-21.)

Ortho argues summary judgment is proper with respect to this claim because there is no evidence that testing on acetozolamide would have been material to the examiner's analysis. It argues the compound is more remote than those in the Kachetkov prior art references, which were disclosed to the PTO and would have been cumulative of that prior art reference. (Ortho's Br. at 17-21.)

As stated supra, the applicants for the '006 patent were obligated to disclose only information that was material to the examiner's determination of whether or not to grant the patent. Dayco Prods., 329 F.3d at 1363; see also 37 C.F.R. § 1.56(b) (providing information is material "when it is not cumulative to information already of record . . . in the application, and" it "establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim . . . ."). Mylan's assertion that the claimed invention would have been obvious from the acetazolamide testing, requires the Court to consider whether or not a patent examiner would have found in that testing (1) a suggestion or motivation in the prior art reference or "in the knowledge generally available to one or ordinary skill in the art," to modify the reference or combine its teachings; (2) a reasonable expectation of success in doing so; and (3) the prior art reference "must teach or suggest all the claim limitations" of the claimed

---

compound described in claim 1 [of topiramate]; correct?
A. Yes.
Q. Rather, your opinion assumes that someone arrives at that compound just by chance?
A. If you're lucky.

(Lohrenz Decl. Ex. N, Supuran Dep. Tr. 134:17-24.)

invention. MPEP § 706.02(j).

While Dr. Supuran's testimony suggests a similarity in utility between the compounds, it does not necessarily show that teaching found in the acetazolamide testing would motivate one reasonably skilled in the art to develop topiramate. Given the lack of evidence to support Mylan's inequitable conduct claim related to the acetazolamide testing, and keeping in mind the "clear and convincing" standard required to prove inequitable conduct, Digital Control, 437 F.3d at 1313, the Court is satisfied that summary judgment on this claim is proper.

Moreover, the acetazolamide compound was cumulative of the Kochetkov prior art references. The moiety that Mylan argues would make acetazolamide material to the topiramate strucure, the SO_2NH_2 moiety, was also present in the Kochetkov compound, however, the Kochetkov compound did not, on that basis, prevent the '006 patent from issuing. Thus, acetazolamide was cumulative of prior art references already before the PTO. See 37 C.F.R. § 1.56(b) (limiting material information to that which is not "already of record" before the PTO). Under the same reasoning, the acetazolamide compound would have been immaterial to the examiner's determination of the '006 application. Since acetazolamide would have been cumulative of prior art already before the PTO and immaterial to the examiner's determination, there would have been no basis for supplemental evidence related to acetazolamide, such as the comparison testing, to be submitted. For this further reason, summary judgment is appropriate with respect to Mylan's inequitable conduct claim based on the acetazolamide testing.

iii. Dr. Gardocki's Role in the Development of Topiramate

Mylan claims that Dr. Maryannoff credited his co-inventor, Dr. Gardocki, with recognizing the structural similarity between topiramate and acetazolamide and, on that basis,

testing topiramate and discovering that it had anticonvulsive properties. (Harth Decl., Ex. E, Scientific Article by Dodgson, *et al.*, at OMP 018844; Ex. F, Scientific Article by Shank, *et al.*, at OMP 026576; Ex. B at OMP 083168.) At his deposition, however, Dr. Maryanoff testified that topiramate was discovered as a result of "broad screening" that was administered to every new compound synthesized by Ortho-McNeil and included anticonvulsive testing. (Harth Conf. Decl., Ex. G, Gardocki Dep. Tr. at 29:23-32:15; 40:18-41:3; 52:7-55:25; 85:23-90:8.) Mylan argues that Dr. Gardocki's "storified" role represented an effort to conceal that topiramate's anticonvulsive properties were discovered though routine "broad screening," rather than as a result of some special insight. (Mylan's Br.22-23.) Accordingly, Mylan argues listing Dr. Gardocki as an "inventor" on the patent application was a misrepresentation and amounted to inequitable conduct.

In Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998), the Court of Appeals for the Federal Circuit described the requirements for inventorship as follows:

> A patented invention may be the work of two or more joint inventors. See 35 U.S.C. § 116 (1994). Because "[c]onception is the touchstone of inventorship," each joint inventor must generally contribute to the conception of the invention. Burroughs Wellcome Co. v. Barr Lab., Inc., 40 F.3d 1223, 1227-28, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994). "Conception is the 'formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.'" Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376, 231 USPQ 81, 87 (Fed. Cir. 1986) (quoting 1 Robinson on Patents 532 (1890)). An idea is sufficiently "definite and permanent" when "only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." Burroughs Wellcome, 40 F.3d at 1228.

Id. at 1460. Moreover, "[o]ne does not qualify as a joint inventor merely by assisting the actual

inventor." Bd. of Educ. ex rel. Bd. of Trs. of Florida State Univ. v. Am. Bioscience, Inc., 333 F.3d 1330, 1338 (Fed. Cir. 2003) (citation omitted). The issuance of a patent creates a presumption that the named inventors are the true and only inventors. Ethicon, Inc., 135 F.3d at 1460. "[T]he burden of showing misjoinder or nonjoinder of inventors is a heavy one and must be proved by clear and convincing evidence." Am. Bioscience, Inc., 333 F.3d at 1337 (citations omitted). Applying these principles, the Court finds that the alleged misjoinder of Dr. Gardocki, under these circumstances, cannot form the basis of an inequitable conduct claim.

Notwithstanding Dr. Maryanoff's "storified" version of Dr. Gardocki's role in conceiving of topiramate, Dr. Gardocki qualifies as an "inventor" under Section 115. Ortho has produced evidence that Dr. Gardocki was involved in the conception of topiramate as a therapeutic agent for the treatment of seizures. For example, Dr. Gardocki authored internal reports evaluating the results of "preliminary screening" that "revealed anticonvulsant activity" and further evaluated topiramate as a potential "therapeutic agent for treatment of seizure disorders." (Lohrenz Decl., Ex. H at OMP 029014.) Dr. Gardocki further testified that he contributed to the idea that the '006 patent "had anticonvulsant activity in animals." (Lohrenz Decl., Ex. F., Gardocki Dep. Tr. at 96:9-21.) Given the presumption that Dr. Gardocki is a true inventor, Ethicon, Inc., 135 F.3d at 1460, and Mylan's burden to prove otherwise by clear and convincing evidence, Am. Bioscience, Inc., 333 F.3d at 1337, the Court finds Dr. Maryanoff's testimony that he had historically "storified" Gardocki's role insufficient to support an inequitable conduct claim.

iv. The Jenkins and Shuman Materials

Finally, Mylan asserts that the applicants' failure to disclose Dr. Maryanoff's reliance on the works of Jenkins and Shuman amounted to inequitable conduct. Mylan argues the works

show that a sulfamoylation reaction would be easy to accomplish. (Mylan's Br. at 21-22.) It argues they would have been material to the examiner's determination because Dr. Maryanoff was motivated by the sulfamoylation of nucleocidin that they describe to perform the fructose sulfamoylation that led to topiramate. (Id. at 22.) In support of this, Mylan will introduce testimony of Dr. Anderson, their "expert carbohydrate chemist," that it would have been obvious to one skilled in the art, based on the teachings in the Jenkins and Shuman materials, "that the sulfamoylation of the primary OH group in fructose derivatives would be easy to accomplish." (Id.)

Mylan's proposed evidence does not meet the materiality requirement. The question here is not whether or not one of reasonable skill in the art would find it easy to make the claimed compound based on the prior art, but whether or not the prior art suggests the claimed invention. In In re Fine, 837 F.2d 1071 (Fed. Cir. 1988), the Court of Appeals for the Federal Circuit stated:

> Obviousness is tested by "what the combined teachings of the references would have suggested to those of ordinary skill in the art." In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). But it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." ACS Hosp. Sys., 732 F.2d at 1577, 221 USPQ at 933. And "teachings of references can be combined *only* if there is some suggestion or incentive to do so." Id.

Id. at 1075 (emphasis in original).

Dr. Anderson's testimony that one reasonably skilled in the art would find the sulfamoylation of the primary OH group in fructose, a process that led to the development of topiramate, "easy to accomplish" does not tend to show that it "suggested" topiramate. Stated differently, while Jenkins and Schuman materials may teach a method to make topiramate, they

do not suggest or motivate one to do so. In this regard, the Court of Appeals for the Federal Circuit has stated that a prior art reference that discloses the mere existence of a technique by which the claimed invention may be carried out is insufficient to support a prima facie case of obviousness. In re Deuel. 51 F.3d 1552, 1559 (Fed. Cir. 1995). Given that the Schuman and Jenkins material could not have supported a prima facie case of obviousness, they would not have been important to, and would not have affected, the examiner's determination regarding the '006 patent. Accordingly, summary judgment is proper as to Mylan's inequitable conduct affirmative defense based on the applicants' failure to disclose the Jenkins and Schuman materials.

Moreover, saying that topiramate would be easy to accomplish through the process taught by the Schuman and Jenkins references assumes that one sought to develop topiramate in the first instance. Ecolochem, Inc. v. So. Cal. Edison Co., 227 F.3d 1361, 1371-72 (Fed. Cir. 2000) (holding that "[c]ombining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability-the essence of hindsight.") (citations omitted). In this regard, the Court is mindful that "[t]o imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." W.L. Gore & Assoc. v. Garlock, Inc., 721 F.2d 1540, 1553 (Fed. Cir. 1983); see also In re Fine, 837 F.2d at 1075 (warning against "pick[ing] and choos[ing] among isolated disclosures in the prior art" and "fall[ing] victim to the insidious effect of a hindsight syndrome.") (citation omitted). As stated previously, while the Schuman and Jenkins

references may teach a method that was used to create topiramate, nothing therein tends to prove that they "suggest" topiramate. Holding that they were material omissions because they teach a process by which topiramate would be "easy to accomplish" would presuppose knowledge about the claimed compound and, therefore, would be to succumb to the "hindsight syndrome" proscribed by W.L. Gore. For this further reason, summary judgment is appropriate on the inequitable conduct affirmative defense based on the Jenkins and Schuman materials.

Lastly, the Court agrees with Ortho that the technique at issue in the Jenkins and Schuman materials, the sulfamoylation of sugar, was also disclosed in the Kochetkov prior art references. The Court notes that information is material to an examiner's determination of whether or not to grant a patent application only when it "is not cumulative to information already of record or being made of record in the application." 37 C.F.R. § 1.56(b). In this case, the technique at issue was disclosed by the Kochetkov prior art references that were already before the PTO and, therefore, were cumulative of that prior art. For this further reason, these prior art references were not material and summary judgment is appropriate on this affirmative defense.

IV. CONCLUSION

For all of the foregoing reasons, plaintiff's motion for partial summary judgment is **GRANTED**, and defendants' affirmative defense based on inequitable conduct shall be **DISMISSED**.

Dated: May 30, 2006

/s/Stanley R. Chesler
United States District Judge